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**ISO/TC 84/WG 3 ad hoc 5**  
**Needle-free injectors for medical use**

**N3**

**Convenor: Paul Jansen, USA**  
**Secretary: Lars Brogaard, Denmark**

**July 1999**

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### **Review of current jet injection technology**

This review is made by Linda D'Antonio according to the decision taken on the first meeting of ad hoc group 5. The document is submitted for information.

## **Research on Jet Injector Companies**

### **1) Company: Bioject and Vitajet**

#### **Web Page:**

**Address:** 7620 SW Bridgeport Rd.  
Portland, OR 97224

**Phone:** 1-800-683-7221

**CEO:** James C. O'Shea

**Stock Information:** As of February of '99 stock for the co. was trading at around 63 cents a share down from its \$6.65 a share. In 1997, the co. reported a loss of \$4.6 million, which was an improvement from its \$5.6 million the co. lost in 1996 and a loss of \$5.6 million in 1995.

**Company Profile:** Vitajet was founded in 1977, with intentions to design, manufacture and service needle-free hypodermic jet injectors. Has produced systems for mass immunizations, the world's largest market. Has both experience in the public health sector (vaccines) and the home self-injection market (insulin). In April of 1998, Bioject Inc purchased Vitajet.

#### **- Product: Vitajet 3**

**Use:** Not recommended for children under the age of two.

**Crystal Check and Trade:** This is the company's exclusive technology that allows the user to visually confirm the correct dosage amount and to confirm that the medication has been dispensed, acts like a syringe.

**Disposal:** Totally disposable, eliminates the need for maintenance. Has disposable nozzle tips and after 7 days of use you must remove the old and replace it with new ones. It is a snap and click design.

**Medications used:** Insulin is the only medication that is currently being used in the Vitajet 3. Although in Asia, Europe, and South America the system is being used to administer human health hormones.

**Safety:** Has been clinically tested and cleared for marketing in the U.S. by the FDA.

**Dosages:** Smallest = 2 units  
Largest = 50 units

**Warranty:** Warranties by Bioject Inc. for two years from date of purchase. 30 day money back guarantee.

**Cost:** \$399.00, includes a one-month supply of Crystal Check nozzles, vial holders, training video, manual, and carrying case.

#### **- Product: Biojector 2000**

**Mechanics:** Injects medication intramuscularly or subcutaneously without a needle. Uses compressed Co2 as a power source as it goes through a tiny orifice in a fraction of a second.

**Disposal:** Uses a sterile single use syringe, plastic, which eliminates cross infection. A new syringe is inserted after each use.

**Sterilization and Maintenance:** Not necessary.

**Product Specifications:**

**Size:** 8.5 inches

**Weight:** 20.5 ounces (580 grams)

**Power Source:** Co2 Cartridge

**Injections per Co2 Cartridge:** 6 - 10

**Pressure Indicator:** Yes

**Warranty:** 1 year

**Target Market:** Hospitals were the original target, but they resisted sales attempts with claims that the high tech product cost too much. The Biojector 2000 sells for nearly three times the normal n/s technology. Rather than hospitals public health agencies are now being looked at, unlike hospitals they have more money to spend on improved technology. This is because health agencies are more concerned with getting people vaccinated and hospitals are more cost conscious. They are also targeting flu immunization markets in the US.

**Dosages:** Holds a max of 1 cc of fluid.

- 2) **Company:** National Medical Products (NMP)

**Web Page:**

**Address:** 57 Parker Street  
Irvine, CA 92718

**Phone:** 1-714-768-1147

**Company Profile:** Company was founded in 1989 and is automated to meet manufacturing demands of product for the first two years. The primary objectives of the company is to bring the conceived product to a clinically proven and approved marketable entity, achieve required manufacturing capabilities and introduce the device into commercial distribution.

**Product:** J-Tip

**Use:** It is loaded by the patient then placed against the skin at the selected site and is then triggered by thumb pressure on a trigger. The medication is forced into subcutaneous tissue by high-pressure gas in a fraction of a second.

**Target Market:** Home health care, diabetics.

**Product Specifications:**

**Size:** 4in. in length and weighs 9 grams

**Capacity:** .02 to .25 ml

**Power Source:** Co2 Cartridge

**Operating Temp.:** 50 - 100F or 10 - 37C

**Materials:** All plastic

**Warranty:** 1 year

**Disposal:** Single use disposable syringe. When the injection is complete, injector is discarded. vial, transporter and adapter are also discarded; whole unit is disposable.

3) **Company:** Visionary Medical Products Corporation (VMPC)

**Web Page:**

**Address:** P.O. Box 6911  
Beverly Hills, CA 90212 (Based in Reno, Nevada)

**Phone:** 310-201-0800

**Company Profile:** VMPC designs, develops, licenses, and markets, proprietary medical devices. They have special expertise in medication administration, medical safety protection and devices for the management and treatment of diabetes. They have many patents and have licensed medical devices to many of the world's largest pharmaceutical and medical products manufacturers. Currently under agreement with Pasteur Merieux Connaught for his company's proprietary use to deliver the influenza vaccine.

**Product:** PenJet/Micro

**Target Markets:** Designed for use in mass inoculations and specialized uses, such as in first aid kits.

**Disposal:** Single use and totally disposable.

**Product Specifications:**

**Size:** 4 inches in length and about as thick as a pen, 2/3 the size of Penjet.

**Power Source:** Self-contained compressed inert gas.

**Dosage:** Up to .5 cc, pre-filled

**Product:** Penjet

**Target Market:** To those in need of the influenza vaccination, mass inoculations, and specialized uses.

**Disposal:** Single use

**Product Specifications:**

**Size:** Size of a pen.

**Power Source:** Self-contained compressed inert gas.

**Dosage:** Subcutaneous doses up to 1.0 cc.

**Injections per Cartridge:** 12 - 14 or a rechargeable high capacity housing unit good for 150 injections before replacing cylinder.

**Storing Temp:** 37-157F, designed for long term refrigeration.

**Use:** Disposable injector prefilled with the influenza vaccine for injection w/o a needle.

Has the ability to regulate injection depth or penetration,

**Cost:** Comparable to conventional N/S because of disposable ampules.

**Safety:** No threat of cross contamination is present. The pressure sensing deployment ensures the proper setting of the injector face against the skin surface before medication is delivered. This assures safe use for those that are inexperienced with the system, such as children.

4) **Company:** Medi-Ject

**Web Page:**

**Address:** 161 Cheshire Ln.  
Suite 100  
Minneapolis, MN 55441

**Phone:** 1-800-328-3074

**Company Profile:** One of the world's leaders in needle-free injection systems for drug delivery. Medi-Ject pioneered the development of needle-free injection use for individual use in 1979.

**Product:** Medi-Jector

**Target Market:** Used worldwide by persons with diabetes. In Europe and Japan the product is used for daily injections of human growth hormones.

**Use:** Uses pressure to create a micro-thin column of insulin, which penetrates through the skin and disperses into subcutaneous tissue in less than half a second.

**Cost:** \$595

**Product Specifications:**

**Dosage:** Can deliver single or mixed insulin doses, from 2 to 50 units of U-100 insulin.

**Adjustments:** Dosage adjustments in 1/2 unit increments.

**Warranty:** One-year warranty, 30-day money back guarantee.

**Power Source:** Gas spring.

**Settings:** 15 pressure settings.

**Cleaning:** No regular cleaning or maintenance required.

**Disposal:** New adapter for each insulin bottle, reusable orifice and chamber.

5) **Company:** Evans Enterprise

**Web Page:**

**Address:** 1293 Sunset Rd.  
Mayfield Heights, OH 44124

**Phone:** 1-440-473-1110

**Product:** Med-E-Jet

**Use:** Automatic, to operate place nozzle against the injection site and pull the trigger. Gives IM, SC, and IC injections by changing the injection head.

**Dosage:** Delivers 20 doses of 1 ml and up to 50 smaller doses.

**Sterilization:** Injection head must be sterilized. In hospital usage, weekly intervals of cleaning are necessary.

**Power Source:** No electricity.

6) **Company:** Robbins Instruments

**Web Page:**

**Address:** 23 Bis Rue Louis Barthou  
64000 PAU, France

**Phone:** 33-0-5-59-27-22-70

**Product:** Dermojet (4 different models are available)

**Model 1:** The Standard Dermojet

**Parts:** Syringe body, injection head, transparent barrel, and a clamping ring.

**Shape:** Cylinder.

**Dosage:** Capacity of 0,4 ml.

**Temp:** Can be sterilized at 140C.

**Weight:** 300 Grams

**Target Market:** Veterinary medicine.

**Model 2:** Dermojet HR

**Temp:** Can be sterilized at 180C max.

**Target Market:** Human medicine (local anaesthetic)

**Model 3:** Automatic Dermojet

**Shape:** Gun

**Target Market:** Veterinary Medicine, Vaccination against Rabbit's Myxomatosis, vaccination of meat in pigs against Aujeszki's disease.

**Dosage:** 0,1ml or 0,2 ml

**Model 4:** Dermojet Polymedical

**Use:** Has an injection head with an adaptor for the Tip Jet interchangeable sterilized injection head.

- 7) **Company:** Equidyne Systems Inc. A owned subsidiary of American Electromedics Corp.

**Web Page:**

**Address:** 116969 Sorrento Valley Rd., Suite J  
San Diego, CA 92121

**Phone:** 619-350-8096

**Company Profile:** Equidyne Systems Inc. has acquired FDA clearance to market the INJEX system in the U.S. In addition, two U.S. patents have been issued for the features of the injector and the entire INJEX system.

**Product:** INJEX

**Use:** This system is designed to replace N/S use and deliver a dose of medication into subcutaneous tissue with virtually no pain.

**Disposal:** Totally disposable, single use disposable ampule.

**Mechanics:** When the trigger is activated a spring is released that propels the drug through a small orifice in the ampule tip and into the skin through a pore. The ampule is then easily removed from the injector and discarded.

**Specifications of product:**

**Dosage:** .02ml - .5ml

**Maintenance:** Ampules can be prefilled by the medication manufacturer for resale through pharmacies and other distribution channels. Ampules can also be delivered empty and sterile for individual filling.

**Target Market:** Diabetic children and children requiring growth hormones.

- 8) **Company:** Weston Medical (UK), Meridan Medical Technologies  
- Meridan acquired N. American manufacturing and marketing rights for INTRAJECT from Weston Medical.

**Web Page:**

**Address:** New Street  
Stradbroke  
Eye  
Suffolk IP21 5JG

**Phone:** + 44 (0) 1379 384 800

**CEO:** Christopher Samler

**Company Profile:** Weston Medical is an UK based company and is currently in discussion with many leading pharmaceutical and biotechnology companies regarding clinical trials with their product. In 1996 they signed a licensing deal with Medeva who is testing their product with the flu vaccination. In 1998 Weston Medical granted their first global license to Hoffmann-La Roche to deliver a compound, pegylated interferon. Also in 1998, the company granted a global license to P&U for the delivery of low molecular weight heparin (LMWH).

**Product:** INTRAJECT

**Use:** To administer the product all you need to do is remove the safety seal and press the injector against the arm or thigh.

**Disposal:** Totally disposable and it cannot be reactivated.

**Power Source:** Compressed Nitrogen expands to activate the system.

**Size:** Half the size of a fountain pen.

**Target Market:** Medicine in early intervention home healthcare and emergency medical technologies, and also provides product development and manufacturing support to the pharmaceutical and biotechnology industries.

9) **Company:** Advantage Health Services, Inc.

**Web Page:**

**Address:** 735 York Road  
Willow Grove, PA 19090-2195

**Phone:** 1-800-809-1389

**Company Profile:** Advantage Health Systems provides medications, supplies, and services.

- **Product:** AdvantaJet

**Use:** A micro-jet stream of insulin mists through the outer skin and into the subcutaneous layer.

**Target Market:** Patients who depend on multiple daily injections of insulin for diabetic care.

**Warranty:** A two year limited warranty, also provides a free loaner or exchange program if necessary.

**Cost:** \$795

**Product Specifications:**

**Dosage:** Range .5-50 units of U-100 insulin.

**Size:** 6 ounces or 172 grams.

**Materials:** Stainless steel and plastic (front tube and power pack).

**Sterilization:** Must be completed on a weekly basis.

**Loading:** Insulin is loaded by attaching the vial and vial adapter to the injector. The number of



each unit loaded appears in the lens. A dot after each number designates a half unit.

**Adjustments:** Has a range of settings depending upon variables such as insulin type, volume, skin type, and injection site.

- **Product:** AdvantaJetES, Extra Strength

**Cost:** \$795

**Use:** For people with tougher skin types.

**Warranty:** 2 years

- **Company:** Health Mor Personal Care Corporation (A subdivision of Advantage Health Services)

**Web Page:** Fejl! Bogmærke er ikke defineret

**Address:** 185 E. North Street  
Bradley, IL 60915  
USA

**Phone:** 1-800-662-2471

**Product:** GentleJet

**Target Market:** Is especially designed for use by kids with diabetes.

**Dosage:** Can deliver .5-50 units of insulin.

**Sterilization:** Must be sterilized once a week with isopropyl alcohol.

**Warranty:** Two years, but damage due to dry firing is not covered by warranty.

**Cost:** \$795

10) **Company:** PowderJect

**Web Page:**

**Address:** Based in Oxford, UK with operations in Fremont, California, and Madison, Wisconsin.

**CEO:** Dr. Paul Drayson

**Company Profile:** PowderJect is a development-stage drug and vaccine delivery company specializing in the needleless powder injection of drugs, biopharmaceuticals, vaccines, and gene therapies.

**Product:** PowderJect

**Use:** The system aims to deliver intra-dermal injections.

**Power Source:** Delivery works by the acceleration of fine particles to supersonic speed within a helium gas jet.

**Safety:** Has not shown any skin damage such as bruising or bleeding and risk of cross contamination is eliminated.

**Storage:** Does not require refrigeration or reconstitution before delivery because of the dry powder form inside the device.

**Target Market:** The delivery of DNA to humans and the company is currently running tests.

**Power Source:** Actuation of the system opens a gas canister, which allows helium gas at high pressure to enter a chamber at the end of which is a drug cassette containing the powered drug between two plastic membranes.

11) **Company:** Keystone

**Web Page:**

**Address:** 616 Hollywood Avenue  
Cherry Hill, NJ 08002

**Phone:** 1-800-333-3131

**Product:** SyriJet

**Use:** Assures reliable anesthesia for successful operative and surgical procedures in both upper and lower anterior areas and for all procedures on deciduous teeth.

**Dosage:** 0-.2cc

**Cleaning:** Must be done at least once a week.

12) **Company:** PATH, The Program for Appropriate Technology in Health

**Web Page:** [www.path.org](http://www.path.org)

**Address:** 4 Nickerson Street  
Seattle, WA

- Also has offices in Washington DC, Indonesia, Kenya, Phillipines, Thailand and Ukraine.

**Phone:** 1-206-285-3500

**Company Profile:** PATH is a nonprofit, international organization that develops technically and culturally appropriate solutions to public health problems. They work mostly with reproductive health and communicable disease issues. They also work in partnership with community based groups, private sector companies, governmental and non-governmental organizations, funding agencies and health services, including clinics and ministries of health.

**Product:** Medivax

**Mechanics:** A needle free, self contained, low cost, safe injection device suitable for use in routine immunization health clinics or national immunization day service centers where up to 1,000 injections may be given in a day.

**Disposal:** Has a disposable fluid path to ensure sterile injections.

**Dosages:** Can deliver any vaccine with .5cc of liquid for a subcutaneous or intramuscular injection.